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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,233	MARTH ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3, 8-13, 18, 19 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using lectins that bind a glycoprotein where the lectin does not bind, classified in class 435, subclass 7.1

II. Claims 3, 8-14 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using antibodies that bind a glycoprotein where the antibody does not bind, classified in class 435, subclass 7.1.

III. Claims 3, 8-13 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using acceptor binding moiety of a glycosyltransferase that binds a glycoprotein where the acceptor binding moiety does not bind, classified in class 435, subclass 7.1.

IV. Claims 3, 8-13 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using lectins that bind to a glycolipid where the lectin does not bind, classified in class 435, subclass 7.1

V. Claims 3, 8-14 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using antibodies that bind to a glycolipid where the antibody does not bind, classified in class 435, subclass 7.1.

VI. Claims 3, 8-13 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using acceptor binding moiety of a glycosyltransferase that binds to a glycolipd where the acceptor moiety does not bind, classified in class 435, subclass 7.1.

VII. Claims 3, 8-13 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using lectins that binds to a proteoglycan where the lectin does not bind, classified in class 435, subclass 7.1

VIII. Claims 3, 8-14 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using antibodies that binds to a proteoglycan where the antibody does not bind, classified in class 435, subclass 7.1.

IX. Claims 3, 8-13 and 23, drawn to methods of diagnosing a genetically transitted glycosylation disorder using acceptor binding moiety of a glycosyltransferase that binds to a proteoglycan where the acceptor moiety does not bind, classified in class 435, subclass 7.1.

X. Claims 15 and 16 drawn to methods of diagnosing a genetically transitted glycosylation disorder using antibodies that bind to a polypeptide where the antibody does bind, classified in class 435, subclass 7.1.

XI. Claims 18, drawn to methods of diagnosing Congenital Dyserthropietic Anemia where there is reduced binding of E-PHA, classified in class 435, subclass 7.1

XII. Claim 19, drawn to methods of diagnosing Congenital Dyserthropietic Anemia where there is increased binding of E-PHA, classified in class 435, subclass 7.1.

XIII. Claims 21, drawn to methods of diagnosing Carbohydrate Deficient Glycoprotein Syndrome Type II where there is reduced binding of E-PHA lectin, classified in class 435, subclass 7.1

XIV. Claims 22, drawn to methods of diagnosing Carbohydrate Deficient Glycoprotein Syndrome Type II where there is increased binding of ConA lectin, classified in class 435, subclass 7.1

XV. Claims 24 and 25, drawn to methods of monitoring the course of treatment of a glycosylation disorder in a mammal, classified in class 435, subclass 7.1.

XVI. Claims 27-29, drawn to methods of detecting a genetically transmitted B lymphocyte dysfunction by detecting binding of a reagent to a glycoconjugate, classified in class 435, subclass 7.1.

XVII. Claims 31 and 32, drawn to methods of detecting a genetically transmitted T lymphocyte dysfunction by detecting increased binding of a reagent to a glycoconjugate, classified in class 435, subclass 7.1.

XVIII. Claims 33 and 34, drawn to methods of detecting a genetically transmitted T lymphocyte dysfunction by detecting reduced binding of a reagent to a glycoconjugate, classified in class 435, subclass 7.1.

XIX. Claims 35-37, drawn to methods of detecting a genetically transmitted myeloid deficiency by detecting reduced binding of a reagent to a glycoconjugate, classified in class 435, subclass 7.1.

XX. Claim 42, drawn to a chimeric animal, which comprises cells having a defect in a gene for an oligosaccharide transferase, classified in class 800, subclass 14.

XXI. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for an α-glucosidase I, classified in class 800, subclass 14.

XXII. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for an α-glucosidase II, classified in class 800, subclass 14.

XXIII. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for an ER α-1,2-mannosidase, classified in class 800, subclass 14.

XXIV. Claim 42, drawn to a chimeric animal, which comprises cells having a defect in a gene for an N-acetylglucosaminyl-phosphotransferase, classified in class 800, subclass 14.

XXV. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for an N-acetylglucosamine-1-phophodiester α-N-acetylglucosaminidase, classified in class 800, subclass 14.

XXVI. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for a Golgi α-mannosidase I, classified in class 800, subclass 14.

XXVII. Claim 42, drawn to a chimeric animal, which comprises cells having a defect in a gene for an N-acetylglucosaminyltransferase I , classified in class 800, subclass 14.

XXVIII. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for a Golgi α-mannosidase II, classified in class 800, subclass 14.

XXVIX. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for an N-acetylglucosaminyltransferase II , classified in class 800, subclass 14.

XXX. Claim 42, drawn to a chimeric animal, which comprises cells having a defect in a gene for a fucosyltransferase, classified in class 800, subclass 14.

XXXI. Claim 42, drawn to a chimeric animal which comprises cells having a defect in a gene for a galactosyltransferase , classified in class 800, subclass 14.

XXXII. Claim 42, drawn to a chimeric animal, which comprises cells having a defect in a gene for a glucosyltransferase, classified in class 800, subclass 14.

XXXIII. Claim 43 and 44, drawn to a chimeric animal which comprises cells having a defect an MGAT 2 gene, classified in class 800, subclass 14.

XXXIV. Claim 43 and 45, drawn to a chimeric animal which comprises cells having a defect an ST6Gal sialytransferase gene, classified in class 800, subclass 14.

XXXV. Claim 43 and 46, drawn to a chimeric animal which comprises cells having a defect an ST3Gal sialytransferase gene, classified in class 800, subclass 14.

XXXVI. Claim 48-51, drawn to a kit for diagnosing a glycosylation disorder in a mammal, classified in class 514, subclass 1.

The inventions are distinct, each from the other because:

Inventions I-XIX to method of diagnosing, monitoring or detecting various conditions associated with glycosylation disorders and inventions XX-XXXV to transgenic mammals having a defective gene encoding a protein involved in a glycosylation biosynthetic pathway are mutually exclusive and independent methods. Methods of detection or monitoring require materially different and separate protocols the transgenic mammal. Further the method is not required for the animal and the animal is not needed for the methods.

Inventions XXXV1 and any of I-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit can be used to purified components by specific binding.

Inventions XX-XXXV and XXXVI are mutually exclusive and independent. The transgenic mammals of inventions XX-XXV are not needed for the kit of invention XXXVI and vice versa.

Each of inventions I-XIV and XV-XIX are mutually exclusive and independent methods of diagnosing and detecting. Each of these methods is directed to using materially different and separate reagents to diagnose or detect materially different and separate diseases or conditions. Further none of the methods is required for the implementation of any other method.

Each of inventions I-XIV and XIX, and inventions XV-XVIII are mutually exclusive and independent methods of diagnosing and detecting, and monitoring, respectively. These

methods each involve materially different and separate protocols. Further, none of the methods are involved for any of the other methods.

Claims 1, 2 and 4-7 link(s) inventions I-X; claim 1 and 17 link(s) inventions XI and XII; claims 1 and 20 link(s) inventions XIII and XIV, claim 26 link(s) inventions XVI and XIX; claims 26 and 30 link(s) inventions VII and XVIII and claims 38-41 link(s) inventions XX-XXV.

The restriction requirements among the linked inventions is subject to the nonallowance of the linking claim(s) as given above. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

June 28, 2004